



HAGENS BERMAN

Kristen A. Johnson  
HAGENS BERMAN SOBOL SHAPIRO LLP  
55 CAMBRIDGE PARKWAY, SUITE 301  
CAMBRIDGE, MA 02142  
www.hbsslaw.com  
Direct (617) 475-1961  
kristenj@hbsslaw.com

February 13, 2015

**VIA HAND DELIVERY AND ECF**

The Honorable Rya W. Zobel  
United States District Judge  
District of Massachusetts  
John Joseph Moakley Federal Courthouse  
1 Courthouse Way, 5<sup>th</sup> Floor  
Boston, MA 02210

The Honorable Jennifer C. Boal  
United States Magistrate Judge  
District of Massachusetts  
John Joseph Moakley Federal Courthouse  
1 Courthouse Way, 5<sup>th</sup> Floor  
Boston, MA 02210

Re: *In re New England Compounding Pharmacy, Inc. Products Liab. Litig.*,  
Master Dkt.: 1:13-md-02419-RWZ; MDL No. 2419

Dear Judge Zobel and Judge Boal:

On behalf of the Plaintiffs Steering Committee (“PSC”), the Official Creditors’ Committee (“OCC”), and the Chapter 11 Trustee (“Trustee”), I write to respond to your suggestion at the January 14, 2015 status conference that Magistrate Judge Kenneth P. Neiman be designated in the NECC bankruptcy plan (“NECC Plan”) to rule on appeals from tort claim determinations made in the first instance by the Settlement Administrator. I also write to respond to your preliminary view that Judge Zobel would then be in a position to review the decisions of Judge Neiman.

First, the PSC, OCC, and Trustee agree that Judge Neiman would be an excellent candidate for the position of “Appeals Administrator.”<sup>1</sup> If he and this Court are comfortable with the scope of duties outlined in the NECC Plan (and as described below and in the attached Claim Resolution Facility Procedures)<sup>2</sup>, then the NECC Plan contemplates that the District Court – upon the Plan effective date – would appoint Judge Neiman as the Appeals Administrator pursuant to 28 U.S.C.A. § 636(b)(3).<sup>3</sup>

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<sup>1</sup> Our previous use of the term “Special Master” may have created some confusion due to the provisions of Fed. R. Civ. P. 53. We have changed the title to “Appeals Administrator,” to clarify the role contemplated by the NECC Plan.

<sup>2</sup> The Claims Resolution Facility Procedures are Exhibit A to the Tort Trust Agreement, and were filed today with both the MDL and Bankruptcy Courts as part of the Plan Supplement (13-md-02419, ECF No. 1694-3; 12-br-19882, ECF No. 1123-3).

<sup>3</sup> See 28 U.S.C. § 636(b)(3) (“A magistrate judge may be assigned such additional duties as are not inconsistent with the Constitution and laws of the United States.”) See also Rules for United States Magistrate Judges in the United States District Court for the District of Massachusetts (“Local Rules Mag. J.”), Rule 5 (“The enumeration of

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Second, the PSC, OCC, and Trustee wish to clarify the scope of the Appeals Administrator position described in the NECC Plan.

**A. The Role of the Appeals Administrator.**

The NECC Plan provides for a multi-level review of claims submitted by tort victims. There will first be an initial determination by the settlement administrator. If a claim is denied in whole or in part, the claimant is provided the opportunity to cure any deficiency in the claim identified by the Settlement Administrator, to request reconsideration of the original claim and supporting materials, or request that the claim be considered under a different settlement matrix category than the original claim. If the claim is then finally denied, in whole or in part, by the Settlement Administrator, the claimant is afforded a *de novo* review of his or her claim by the Appeals Administrator (Judge Neiman). Determinations of the Appeals Administrator are final and binding.

The NECC Plan does not provide for judicial review of the Appeals Administrator's final determinations. While the NECC Plan does provide that the District Court will retain jurisdiction to resolve certain issues concerning the NECC Tort Trust Agreement, the Plan does *not* contemplate that decisions rendered by Judge Neiman (or any other person appointed to the position of Appeals Administrator) will be subject to review by Judge Zobel.

The PSC, OCC, and Trustee believe that there are a number of practical considerations that counsel against further review by Judge Zobel. Providing claimants a third review of their claim would be counter-productive in the context of the proposed bankruptcy reorganization. The availability of such review would likely prompt more appeals, may introduce more uncertainty into the calculation of the initial payments to victims,<sup>4</sup> and—most importantly—would potentially further delay the final distribution of money to victims. It may also increase the costs of settlement administration in that the PSC and Tort Trustee may have to become involved in the further review process.

**B. Designating Judge Neiman as the Appeals Administrator is consistent with the statute and rules governing magistrate judges.**

The fact that the NECC Plan does not contemplate appeals to Judge Zobel from the Appeals Administrator's final decisions does not disqualify Judge Neiman (or any other

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specific duties in this section is not to be construed as limiting the referral of any other matter otherwise not inconsistent with the Constitution and laws of the United States.”).

<sup>4</sup> The NECC Plan provides for initial partial payments to victims as their claims are finally allowed and for final payments after all claims determinations have become final.

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magistrate judge) from serving as the Appeals Administrator. Congress gave the district courts a very broad grant of authority in the way magistrate judges may serve. It is hard to imagine an argument that serving as Appeals Administrator for a bankruptcy reorganization plan designed to aid in the resolution of personal injury claims would be “inconsistent with the Constitution and laws of the United States.”<sup>5</sup> Accordingly, the nomination of Judge Neiman to serve as Appeals Administrator is not only a welcome suggestion but is entirely consistent with the Congressional intent in creating the magistrate judge position.

**C. Confirmation of the NECC Plan eliminates the possibility that personal injury claims will be tried in the district court.**

To be sure, all creditors (including the tort plaintiffs) have a right to object to the NECC Plan proposed by the Trustee, and to appeal an order confirming such plan.<sup>6</sup> But with respect to the settled claims against NECC and the nondebtors who contribute to the compensation fund, judicial confirmation of the plan has the consequence of eliminating the possibility of a personal injury or wrongful death lawsuit being tried in the district court against them.<sup>7</sup>

Accordingly, the statutes governing pre-trial decisions that may be referred to magistrate judges, subject to the district court judge’s review,<sup>8</sup> would no longer be implicated. As for Rule 53, which (generally speaking) contemplates that the district court will review the orders or recommendations of the magistrate judge, a magistrate judge is subject to the rule “*only when the order referring a matter to the magistrate judge states that the reference is made under this rule.*”<sup>9</sup> The settlement compensation determinations contemplated by NECC Plan are not made pursuant to Rule 53; accordingly, the provisions of that rule are not implicated.

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<sup>5</sup> 28 U.S.C. § 636(b)(3).

<sup>6</sup> 28 U.S.C. § 158(a).

<sup>7</sup> 28 U.S.C. § 157(b)(5).

<sup>8</sup> See, e.g., 28 U.S.C. § 636(b)(1)(A) (subject to specified exceptions, magistrate judge may “hear and determine any pretrial matter pending before the court” and district court judge “may reconsider any pretrial matter under this subparagraph (A) where it has been shown that the magistrate judge’s order is clearly erroneous or contrary to law”); 28 U.S.C. § 636(b)(1)(B) (magistrate judge may be designated “to conduct hearings, including evidentiary hearings, and to submit to a judge of the court proposed findings of fact and recommendations for the disposition, by a judge of the court, of any motion excepted in subparagraph (A)”); 28 U.S.C. § 636(b)(1)(C) (“A judge of the court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge. The judge may also receive further evidence or recommit the matter to the magistrate judge with instructions.”); 28 U.S.C. § 636(b)(2) (magistrate judge may be designated “serve as a special master pursuant to the applicable provisions of this title and the Federal Rules of Civil Procedure” and, “in any civil case, upon consent of the parties, without regard to the provisions of [Fed. R. Civ. P.] 53(b)”); 28 U.S.C. § 636(c)(1) (“Upon the consent of the parties, ... [a] magistrate judge ... may conduct any or all proceedings in a jury or nonjury civil matter and order the entry of judgment in the case”).

<sup>9</sup> Fed. R. Civ. P. 53(h) (emphasis added).

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**D. Confirmation of the NECC Plan establishes a contractual relationship between the debtor, contributors to the National Settlement Fund, and tort creditors.**

Once a bankruptcy reorganization plan is confirmed, the legal relationships of the parties are permanently changed. “[T]he provisions of a confirmed plan bind the debtor, ... and any creditor, ... whether or not the claim or interest of such creditor ... is impaired under the plan and whether or not such creditor ... has accepted the plan.”<sup>10</sup>

In order to ensure the feasibility of a bankruptcy reorganization plan, a bankruptcy court may also issue a permanent injunction barring claims against certain nondebtors who contribute to the plan estate for purposes of funding the compensation available to tort claimants.<sup>11</sup> The NECC Plan includes such a provision.

Upon plan confirmation, there exists a *contractual* relationship—defined by the plan terms—that may be enforced. In essence, the reorganization plan “is a binding contract between the debtor and the creditors and is subject to the general rules of contract construction and interpretation.”<sup>12</sup>

Here, the contract (*i.e.*, the NECC Plan) provides for an initial determination by the Settlement Administrator, with the right of appeal to the Appeals Administrator. The NECC Plan further provides that the Appeals Administrator’s determination is final. If the NECC Plan is confirmed, then a request for judicial review of the Appeals Administrator’s final determination would require the impermissible; *i.e.*, that the plan be re-written.

**E. Courts regularly approve settlements and plans that do not include an additional layer of judicial review.**

In relevant part, the NECC Plan is not entirely dissimilar from a class action settlement agreement that includes an administrative claims process. Such settlements are routinely

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<sup>10</sup> 11 U.S.C. § 1141(a).

<sup>11</sup> See, e.g., *In re Specialty Equip. Co.*, 3 F.3d 1043, 1047 (7th Cir. 1993); *In re A.H. Robins Co.*, 880 F.2d 694, 702 (4th Cir. 1989), cert. denied, 493 U.S. 959 (1989); *Republic Supply Co. v. Shoaf*, 815 F.2d 1046, 1050 (5th Cir. 1987); *MacArthur Co. v. Johns–Manville Corp.*, 837 F.2d 89, 93 (2d Cir. 1988).

<sup>12</sup> *In re New Seabury Co. Ltd. P’ship*, 450 F.3d 24, 33 (1st Cir. 2006). See also *In re Varat Enters., Inc.*, 81 F.3d 1310, 1317 (4th Cir. 1996) (“Under the Bankruptcy Code, a confirmed plan of reorganization acts like a contract that is binding on all of the parties, debtor and creditors alike.”); *In re Dow Corning Corp.*, 456 F.3d 668, 676 (6th Cir. 2006) (confirmed plan “is effectively a new contract between the debtor and its creditors.”); *Miller v. United States*, 363 F.3d 999, 1004 (9th Cir. 2004) (“A Chapter 11 bankruptcy plan is essentially a contract between the debtor and his creditors, and must be interpreted according to the rules governing the interpretation of contracts.”); *Salmon v. Laser Plot, Inc.*, 189 B.R. 559, 561 (D. Mass. 1995) (“Contract law principles govern the interpretation of a plan of reorganization.”).

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approved, notwithstanding the unavailability of judicial review of individual claim determinations.

For example, the settlement agreement presented for court approval in *Bachman v. Miller*,<sup>13</sup> which involved a class of plaintiffs asserting discrimination claims against the Federal Trade Commission, included an individual claim process similar to that in the proposed NECC Plan. Claimants could present a claim for initial determination by the settlement administrator, and then could appeal that determination to a magistrate judge, whose decision was final and binding.<sup>14</sup> Certain individual claimants whose claims were denied by the settlement administrator and then again by the magistrate judge sought further review by the district court judge. They moved to vacate the provision of the settlement agreement that made the decision of the magistrate judge final on the grounds that such provision denied them a right to a determination of their claim by an Article III judge.<sup>15</sup> The court denied the motion, reasoning as follows:

When Movants brought their claims before the Administrator and then the Magistrate, their requests for relief arose under the settlement agreement. Their claims were no longer Title VII claims because the Movants' rights under Title VII were fully and finally resolved in the settlement agreement, entered into in an Article III forum and approved by an Article III Court. Thus, Movants' allegation that they have a right to have their additional individual claims heard by an Article III Judge must fail and it is unnecessary for the Court to consider whether such a right is waivable or was waived by Movants here.<sup>16</sup>

The same analysis applies to personal injury claims resolved on an administrative basis pursuant to a confirmed bankruptcy reorganization plan. For example, the Dow Corning bankruptcy reorganization plan contained an administrative claims process for individual tort claimants alleging injuries from silicone implants:

Section 8.7 Amended Plan of Reorganization states that [the district court] retains jurisdiction to resolve controversies and disputes regarding the interpretation and implementation of the Plan and the Plan Documents, including the SFA, and, to enter orders regarding the Plan and Plan Documents. (Plan, §§ 8.7.3, 8.7.4, 8.7.5)

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<sup>13</sup> 559 F. Supp. 150 (D.D.C. 1982).

<sup>14</sup> *Id.* at 151-152.

<sup>15</sup> *Id.* at 152.

<sup>16</sup> *Id.* See also *In re Black Farmers Discrimination Litig.*, 950 F. Supp. 2d 196, 201 (D.D.C. 2013) (“*Black Farmers Litig.*”) (denying motion to revise settlement agreement where “parties clearly anticipated, and bargained for, the condition that the Claims Administrator would be responsible for designing and implementing procedures to determine whether claim forms were complete, as well as the condition that all decisions made by the Claims Administrator would be final and unreviewable.”).

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The Plan provides for the establishment of the [Settlement Facility-Dow Corning Trust (“SF-DCT”)], which is governed by the SFA. (Plan, § 1.131) The SF-DCT was established to resolve Settling Personal Injury Claims in accordance with the Plan. (Plan, § 2.01) The SFA and Annex A to the SFA establish the exclusive criteria by which such claims are evaluated, liquidated, allowed and paid. (SFA, § 5.01) Resolution of the claims are set forth under the SFA and corresponding claims resolution procedures in Annex A. (SFA, § 4.01)<sup>17</sup>

As is the case with the proposed NECC Plan, the terms of the Dow Corning plan stated that a claimant was entitled to an initial determination by the settlement administrator, with a right of review by an appeals administrator (identified in the Dow Plan as “Appeals Judge”).<sup>18</sup> The Dow Corning Plan further stated that “The Plan provides that “[t]he decision of the Appeals Judge is final and binding on both Reorganized Dow Corning and the claimant.”<sup>19</sup>

When a personal injury claimant sought judicial review of the Appeals Judge’s decision to deny her claim, the district court held that it was without jurisdiction to review the decision:

The Plan provides no right to appeal to the Court and expressly sets forth that the decision of the Appeals Judge is final and binding on both the Reorganized Dow Corning and the claimants. Allowing the appeal to go forward and to direct the Claims Administrator to pay the rupture claim would be a modification of the Plan language. Generally, the provisions of a confirmed plan bind the debtor and any creditor. 11 U.S.C. § 1141(a). Section 1127(b) is the sole means for modification of a confirmed plan which provides that the proponent of a plan or the reorganized debtor may modify such plan at any time after confirmation of such plan and before substantial consummation of the plan. 11 U.S.C. § 1127(b).

In interpreting a confirmed plan courts use contract principles, since the plan is effectively a new contract between the debtor and its creditors.” *In re Dow Corning Corporation*, 456 F.3d 668, 676 (6th Cir. 2006); 11 U.S.C. § 1141(a). “An agreed order, like a consent decree, is in the nature of a contract, and the interpretation of its terms presents a question of contract interpretation.” *City of Covington v. Covington Landing, Ltd. P’ship*, 71 F.3d 1221, 1227 (6th Cir. 1995). A court construing an order consistent with the parties’ agreement does not exceed its power. *Id.* at 1228.

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<sup>17</sup> *In re Settlement Facility Dow Corning Trust*, No. 07-CV-10191, 2008 WL 905799, at \*2 (E.D. Mich. Mar. 31, 2008) *aff’d sub nom. In re Clark-James*, No. 08-1633, 2009 WL 9532581 (6th Cir. Aug. 6, 2009) (“*Dow Corning Trust*”).

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*



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The Plan's language is clear and unambiguous that the decision of the Appeals Judge is final and binding on the claimants and the Reorganized Dow Corning. The Court has no authority to modify this language. Although bankruptcy courts have broad equitable powers that extend to approving plans of reorganization, these equitable powers are limited by the role of the bankruptcy court, which is to "guide the division of a pie that is too small to allow each creditor to get the slice for which he originally contracted." *In re Dow Corning*, 456 F.3d at 677-78 (quoting *In re Chicago*, 791 F.2d 524, 528 (7th Cir. 1986)). "A bankruptcy court's exercise of its equitable powers is cabined by the provisions of the Bankruptcy Code." *Id.* at 678 (citing *In re Highland Superstores, Inc.*, 154 F.3d 573, 578-79 (6th Cir. 1998)). Ms. Clark-James has not shown that the Court has the authority to exercise its equitable powers outside the clear and plain Plan language. The Court cannot consider Ms. Clark-James' request to review the SF-DCT's decision initially denying her claim since the Plan does not provide for an appeal to this Court to review the SF-DCT's decision.<sup>20</sup>

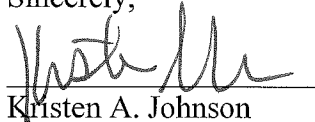
As in the *Bachman*, *Black Farmers Litig.*, and *Dow Corning Trust* cases, upon certification of the NECC Plan Judge Zobel would be without jurisdiction to review or change any final determination by the Appeals Administrator because doing so would re-write the NECC Plan.

#### **F. Alternate candidate.**

In the event that the Court or Judge Neiman elect not to have Judge Neiman appointed as the Appeals Administrator under the NECC Plan, the PSC, OCC, and Trustee have identified an alternate candidate, attorney Kenneth Feinberg, who has offered to provide his services at a reduced rate.

Again, the PSC appreciates the time and attention Your Honors have given to the issues arising in this complex intersection of bankruptcy and tort litigation. We are, as always, available to answer any questions or further address any of the issues raised herein—either in writing or at the next scheduled status conference on February 17, 2015.

Sincerely,



Kristen A. Johnson

HAGENS BERMAN SOBOL SHAPIRO LLP

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<sup>20</sup> *Dow Corning Trust*, 2008 WL 905799, at \*3.

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55 Cambridge Parkway, Suite 301  
Cambridge, MA 02142  
(617) 482-3700  
kristenj@hbsslaw.com

Enclosure(s)

Cc: all counsel (via ECF)



**EXHIBIT A**

**Claims Resolution Facility Procedures**

**EXHIBIT A TO TORT TRUST AGREEMENT:**  
**CLAIMS RESOLUTION FACILITY PROCEDURES**

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## **INTRODUCTION AND GENERAL PROVISIONS**

### **A PERSONAL INJURY AND WRONGFUL DEATH CLAIMS RESOLUTION**

FACILITY (the “Claims Resolution Facility”) is hereby established in accordance with the Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. (the “Plan”) and the Tort Trust Agreement (the “Tort Trust Agreement”), the latter of which establishes the Tort Trust (the “Tort Trust”).<sup>1</sup>

A. Among its provisions, the Plan provides for the resolution, disposition and satisfaction of the Tort Claims, as defined and identified therein, all of which Claims arise out of personal injury or death, in accordance with the Tort Trust Agreement and this Claims Resolution Facility.

B. The Tort Trust Agreement establishes the Tort Trust, the principal purpose of which is to satisfy the Tort Claims.

C. The purposes of the Claims Resolution Facility are (1) to evaluate each of the Tort Claims according to the procedures established herein, with the least practicable cost to the Trust, (2) to determine for each Allowed Tort Claim a fair and equitable compensation amount to be distributed from the Tort Trust, and (3) to effectuate such distributions as expeditiously as possible.

D. To facilitate, effectuate and implement the purposes of the Claims Resolution Facility, Epiq Class Action and Claim Solutions, Inc. (the “National Settlement Administrator”) is hereby retained and appointed to execute the functions described herein in accordance with the terms of the Trust Agreement. The National Settlement Administrator shall oversee all aspects

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<sup>1</sup> Unless the context otherwise requires, all capitalized terms used in these Claims Resolution Facility Procedures and not otherwise defined herein shall have the meanings assigned to them in the Plan and/or the Tort Trust Agreement.

of the Claims Resolution Facility and shall prepare and distribute to the Tort Trustee periodic reports documenting the activities of the Claims Resolution Facility, including reports on Tort Claim submissions and resolution. In the event that the National Settlement Administrator resigns or is removed from office or is otherwise unable to perform the functions of the National Settlement Administrator, a successor National Settlement Administrator shall be appointed by the District Court, as defined in the Tort Trust Agreement, after notice and opportunity to be heard by persons having Tort Claims. The National Settlement Administrator shall receive reasonable compensation in an amount consistent with that of similar functionaries in similar types of proceedings and shall be reimbursed by the Tort Trust for his or her reasonable expenses, including travel expenses, reasonably required and incurred in the performance of his or her duties in accordance with the provisions of the Tort Trust Agreement and the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator. The National Settlement Administrator may employ staff as he/she deems necessary to assist him/her in the performance of his/her duties and the expenses of doing so shall be paid by the Tort Trust in accordance with the provisions of the Tort Trust Agreement and the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator. The National Settlement Administrator may also consult with the Trust Advisory Board in accordance with the provisions of the Tort Trust Agreement. The National Settlement Administrator may also retain consultants in accordance with the provisions of the Tort Trust Agreement and with the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator.

E. To provide for an appeal process from Claim denials, upon entry of an order by the District Court pursuant to 28 U.S.C. § 636, Magistrate Judge Kenneth P. Neiman will be



appointed as Appeals Administrator. If no such order is entered by the District Court within 30 days of the Plan Effective Date, then Kenneth Feinberg, Esq. will be deemed to be appointed as Appeals Administrator. In the event the Appeals Administrator resigns or is removed from office or is otherwise unable to perform the functions of the Appeals Administrator, the District Court shall appoint a successor Appeals Administrator.

F. When notice is required to be sent to a Tort Trust Beneficiary pursuant to these procedures, if the Tort Trust Beneficiary is represented by an attorney as indicated on the Tort Trust Beneficiary's NECC National Compensation Claim Form ("National Compensation Claim Form"), notice shall be provided to both the Tort Trust Beneficiary and the attorney at the addresses listed on the Tort Trust Beneficiary's National Compensation Claim Form, unless updated by the Tort Trust Beneficiary or attorney. Distributions to Tort Trust Beneficiaries who are represented by attorneys shall be made jointly to the Tort Trust Beneficiary and the attorney (or law firm). If a Tort Trust Beneficiary is not represented by an attorney, distributions shall be made payable to the Tort Trust Beneficiary.

G. It shall be the responsibility of the Tort Trust Beneficiary and/or his or her attorney to notify the National Settlement Administrator of address changes of the Tort Trust Beneficiary or the attorney and any other changes with respect to the information provided by the Tort Trust Beneficiary on a completed W-9 form.

H. To the extent that any of these Claims Resolution Facility Procedures conflicts with any provision of the Confirmation Order, the Plan, or the Tort Trust Agreement, the conflicting provision of the Confirmation Order, the Plan, or the Tort Trust Agreement, in that descending order of precedence, shall control.

## **PROCEDURES OF THE CLAIMS RESOLUTION FACILITY**

Pursuant to the Plan and the Tort Trust Agreement, the Tort Trustee shall make distributions as per the terms of the Tort Trust Agreement and these Claims Resolution Facility Procedures. Under the Plan, Confirmation Order, Tort Trust Agreement and these Claims Resolution Facility Procedures, each Tort Trust Beneficiary whose Tort Claim is allowed shall receive his or her individually allocated distribution of the National Fund Net Trust Proceeds. Allocations shall be determined by the National Settlement Administrator, based upon the factors, methodologies and procedures set forth herein.

### **I. Distribution of NECC National Compensation Program Claim Forms**

Within 14 days of the Effective Date, the National Settlement Administrator shall mail a National Compensation Program Claim Form, together with instructions, a Base Point Category and Adjustment Calculation Worksheet, a set of Frequently Asked Questions, and a W-9 Form to the Tort Trust Beneficiaries identified by the Tort Trustee who filed, or who had filed on their behalf, a timely Proof of Claim or Personal Injury and Wrongful Death Claim Information Form (“PITWD Addendum”) in the Chapter 11 Case.

### **II. Procedures for Filing National Compensation Claim Forms**

A. To receive compensation from the Qualified Settlement Fund, Tort Trust Beneficiaries must submit a completed and signed National Compensation Claim Form to the National Settlement Administrator, together with all supporting documentation required, on or before [insert date 120 days after Effective Date], 2015, at 5:00 P.M., Eastern Standard Time. All National Compensation Claim Forms must be received by the National Settlement Administrator by this date and time. No National Compensation Claim Forms may be accepted by the National Settlement Administrator between this date and the date the National Settlement Administrator calculates the Tentative Point Value pursuant to Section VIII.A below, except

upon a showing of excusable neglect as determined by the National Settlement Administrator or, on appeal, to the Appeals Administrator. No National Compensation Claim Forms shall be accepted by the National Settlement Administrator after the date the National Settlement Administrator has calculated the Tentative Point Value pursuant to Section VIII.A herein, except those submitted as Resubmitted Claims pursuant to Section X.A herein. The National Settlement Administrator may also accept as timely National Compensation Claim Forms that are submitted in error (but which are otherwise timely) to the Bankruptcy Court, the District Court, or Donlin Recano.

B. The filing of a National Compensation Claim Form also constitutes participation by that Tort Trust Beneficiary's family members in the primary Tort Trust Beneficiary's Claim or the Class D Estate Claim and Class D Consortium Claims of family members shall be deemed released by the treatment afforded the primary Tort Trust Beneficiary under and in accordance with these Claims Resolution Facility Procedures.

**III. Determination of Eligible Claims Based on Previously Submitted Proofs of Claims or PITWD Addenda in the NECC Bankruptcy Case and a Completed W-9 Form**

A. In order to be eligible to receive compensation from the Tort Trust, a Tort Trust Beneficiary must have previously filed in the Chapter 11 Case a timely Proof of Claim or PITWD Addendum, or had a timely Proof of Claim or PITWD Addendum filed on his or her behalf (the Proof of Claim and PITWD Addenda so filed, collectively, "Timely Proofs of Claim or PITWD Addenda"). Proofs of Claim or PITWD Addenda that were allowed by the Bankruptcy Court to be filed after the Bar Date will be deemed to be Timely Proofs of Claim and PITWD Addenda.

B. The National Settlement Administrator shall conduct an initial review of all National Compensation Claim Forms and the Timely Proofs of Claim and PITWD Addenda filed

by or on behalf of each Tort Trust Beneficiary. If no Timely Proof of Claim or PITWD Addendum was filed by or on behalf of a given Tort Trust Beneficiary, the National Settlement Administrator shall make a final determination denying that Tort Trust Beneficiary's Tort Claim and shall notify the Tort Trust Beneficiary of such final denial and the procedure to appeal to the Appeals Administrator. Notwithstanding anything contained herein to the contrary, a Tort Trust Beneficiary receiving such a final denial may file an appeal with the Appeals Administrator in accordance with the provisions of Section XI below.

C. While conducting the initial review described in Section III.B., herein, the National Settlement Administrator shall also determine if the Tort Trust Beneficiary submitted a completed W-9 form with his or her National Compensation Claim Form. If a completed W-9 form was not submitted by a Tort Trust Beneficiary, the National Settlement Administrator shall notify the Tort Trust Beneficiary that one must be submitted within 90 days of such notice or the claim will be finally denied. In the event of such a final denial, the National Settlement Administrator shall notify the Tort Trust Beneficiary of the final denial and the procedure to appeal to the Appeals Administrator. Notwithstanding anything contained herein to the contrary, a Tort Trust Beneficiary receiving such a final denial may file an appeal with the Appeals Administrator in accordance with the provisions of Section XI herein.

D. All Tort Claims not denied for lack of a Timely Proof of Claim, PITWD Addendum or lack of a completed W-9 form shall be deemed to be "Eligible Claims" and persons holding such Eligible Claims shall be deemed "Eligible Tort Trust Beneficiaries."

#### **IV. Eligible Claims Involving Injections From One or More of the Three Contaminated MPA Lots**

##### **A. Proof of Exposure to One or More of the Three Contaminated MPA Lots**

In order for an Eligible Claim to qualify for any of the seven Base Point Categories described in Section IV.B herein (and thus to be deemed a “Qualified Claim”), the Eligible Tort Trust Beneficiary must submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary received an injection or injections from one or more of lots 05212012@68, 06292012@26 or 08102012@51 (the “Three Contaminated MPA Lots”) of preservative-free methylprednisolone acetate (“MPA”) compounded by New England Compounding Pharmacy (“NECC”), *i.e.* a letter from pain clinic, hospital or doctor’s office informing the Tort Trust Beneficiary that he/she had received an injection from one of the Three Contaminated MPA Lots. Alternatively, if the Eligible Tort Trust Beneficiary (on the National Compensation Claim Form) has requested that the National Settlement Administrator review the lists of patients who received an injection from one of the Three Contaminated MPA Lots that clinics, hospitals and doctor’s offices submitted to the Chapter 11 Trustee pursuant to the *Interim Order Regarding Chapter 11 Trustee’s Motion for an Order Establishing Bar Dates for Filing Proofs of Claim and for Related Relief Concerning Notice by Notice Intermediaries* [Bankr. Dkt. No. 412] (the “Patient Lists”), and the states’ lists of NECC death, stroke, fungal meningitis, spinal or paraspinal infection and/or peripheral joint infection cases (the “State NECC Lists”), and if these lists are available to the National Settlement Administrator, the National Settlement Administrator shall review the relevant Patient List(s) and State NECC lists in order to determine if the Tort Trust Beneficiary’s name is on one of such lists. If the Tort Trust Beneficiary’s name was listed on any such list, this will provide the necessary proof of injection from one of the Three Contaminated MPA Lots.

B. The Seven Base Point Categories

Eligible Tort Trust Beneficiaries who establish that they received an injection or injections from one or more of the Three Contaminated MPA Lots may apply for one of the following seven disease or medical condition categories (“Base Point Categories”):

1. Death After MPA Injection and (1) Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) And/Or (2) Fungal Meningitis (“CATEGORY I”);
2. Non-Death Fungal Meningitis and Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) After MPA Injection (“CATEGORY II”);
3. Non-Death Fungal Meningitis After MPA Injection (“CATEGORY III”);
4. Non-Death Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) After MPA Injection (“CATEGORY IV”);
5. Peripheral Joint (e.g. hip, knee, shoulder, elbow or ankle) Fungal Infection After MPA Injection (“CATEGORY V”);
6. Headache, Word-Finding Difficulty, Nausea/Vomiting, Fever, Neck Stiffness or Pain, Back Pain, Photophobia, Lack of Appetite, Urine Retention, Slurred Speech, Limb Weakness, Numbness, and/or Pain at Injection Site And a Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection (“CATEGORY VI”);
7. No Symptoms or No Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection (“CATEGORY VII”).

C. Additional Proof Required for CATEGORY I Claims

In order for a Qualified Claim made for CATEGORY I to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1) a certified death certificate documenting that the death occurred after injection from one of the Three

Contaminated MPA Lots and with the immediate or underlying cause of death containing one of the following words or phrases: “meningitis,” “meningoencephalitis,” “encephalitis,” “epidural injection,” “methylprednisolone injection,” “steroid injection,” “exsereohilum,” “aspergillus,” “abscess,” or “arachnoiditis;” or (2) a certified death certificate and medical documentation of (a) a diagnosis of fungal meningitis, meningoencephalitis, or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots; and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (3)(a) a certified death certificate and medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block injection); and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (4) a certified death certificate and medical documentation of a cerebrovascular accident/stroke (but not a transient ischemic attack only) occurring after injection from one of the Three Contaminated MPA Lots and on or before December 31, 2012; or (5) a certified death certificate and proof that the Tort Trust Beneficiary was listed on the State NECC Lists of death cases. If such proof is presented, for deaths occurring before September 30, 2013, the National Settlement Administrator shall presume that the death was the result of the MPA injection or complication(s) arising therefrom unless there is



cause to believe that the death was the result of an unrelated event (*i.e.*, auto accident, unrelated illness). For deaths occurring after September 30, 2013 and for deaths where there is a reason to believe that the death resulted from an unrelated event, a certified death certificate and such other proof deemed sufficient by the National Settlement Administrator to establish that the death was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.* the Tort Trust Beneficiary's medical records only state that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. This presumption, as used throughout these Procedures, shall only apply for the purposes of evaluating Tort Claims under these Procedures. This presumption does not affect the calculation of the statute of limitations, statute of repose, or any other time calculation for any other purpose and does not constitute an admission or waiver of any legal position by Tort Trust Beneficiaries. If these requirements are met, the National Settlement Administrator shall award 55 base points to the Tort Trust Beneficiary.

D. Additional Proof Required for CATEGORY II Claims

In order for a Qualified Claim made for CATEGORY II to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of fungal meningitis, meningoencephalitis and/or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing

pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots, and (b) medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block injection); and (c) documentation that the Tort Trust Beneficiary received anti-fungal treatment, or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of fungal meningitis or stroke cases, and was listed on the State NECC Lists of spinal or paraspinal fungal infection cases or was listed on a state list of NECC fungal meningitis and spinal or paraspinal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 40 base points to the Tort Trust Beneficiary.

E. Additional Proof Required for CATEGORY III Claims

In order for a Qualified Claim made for CATEGORY III to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of fungal meningitis, meningoencephalitis and/or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing pleocytosis ( $>5$  white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of fungal meningitis or stroke cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 30 base points to the Tort Trust Beneficiary.

F. Additional Proof Required for CATEGORY IV Claims

In order for a Qualified Claim made for CATEGORY IV to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral

osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block), and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of spinal or paraspinal fungal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 20 base points to the Tort Trust Beneficiary.

G. Additional Proof Required for CATEGORY V Claims

In order for a Qualified Claim made for CATEGORY V to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator medical documentation of (1)(a) a diagnosis of peripheral joint (e.g. hip, knee, shoulder, elbow or ankle) fungal infection (including, but not limited to, osteomyelitis and septic arthritis) after injection from one of the Three Contaminated MPA Lots into the osteoarticular structure of a peripheral

joint (including the bursa and peripheral nerve complex) and (b) that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of peripheral joint fungal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 10 base points to the Tort Trust Beneficiary.

#### H. Additional Proof Required for CATEGORY VI Claims

In order for a Qualified Claim made for CATEGORY VI to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1) contemporaneous medical records documenting that the Tort Trust Beneficiary suffered from one or more of the following symptoms: headache, word-finding difficulty, nausea/vomiting, fever, neck stiffness or pain, back pain, photophobia, lack of appetite, urine retention, slurred speech, limb weakness, numbness, and/or pain at injection site after injection from one of the Three Contaminated MPA Lots and before March 31, 2013 and (2) medical records documenting one lumbar puncture, MRI or CT guided biopsy after injection from one of the Three Contaminated MPA Lots and prior to April 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of

injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient List(s)), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 1 base point to the Tort Trust Beneficiary.

I. Additional Proof Required for CATEGORY VII Claims

There is no additional proof required for CATEGORY VII claims. All Qualified Claims for CATEGORY VII shall be allowed by the National Settlement Administrator and be awarded ½ base point.

J. Upward Adjustments to Qualified Claims

1. *Age Adjustment as of Date of Death for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional point for each year decedent's age was less than 65 on the date of death, up to a maximum of 20 points, as evidenced by the decedent's certified death certificate.

2. *Adjustment for Dependent Children Under 18 for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 5 points for each dependent child under the age of 18 that the decedent had as the date of death, up to a maximum of 15 points.

(a) For this Dependent Children Adjustment, a child is considered to have been dependent on the decedent if he or she was

- (i) Under the age of 18 as of the date of death and listed as a qualifying dependent child on the decedent's 2011 or 2012 federal income tax return; or
- (ii) A natural or legitimate child under the age of 18 as of the date of death; or
- (iii) An adopted child under the age of 18 as of the date of death; or
- (iv) A stepchild under the age of 18 as of the date of death, who lived with the decedent in a regular parent-child relationship at the time of the decedent's death or did not live with the decedent because of medical reasons or to attend school or for other similar reasons; or
- (v) Under the age of 18 as of the date of death who lived with the decedent in a regular parent-child relationship at the time of the decedent's death or did not live with the decedent because of medical reasons, to attend school or other similar reasons, and to whose support the decedent made regular and substantial contributions.

(b) Proof that a child was under 18 as of the date of death may be provided by submitting the decedent's 2011 or 2012 federal tax return, listing the child as a dependent and listing the child's date of birth or a certified birth certificate of the child.

(c) Proof that a child was a dependent may be provided by submitting:

- (i) a copy of the decedent's 2011 or 2012 federal tax return, listing the child as a qualifying dependent child; or
- (ii) a certified birth certificate that indicates that a child was a natural or legitimate child of the decedent. In the event that decedent's name does not appear on the birth certificate, proof may be provided by documentation evidencing a judicial determination of support; or
- (iii) for domestic adoptions, a copy of a revised birth certificate showing the decedent as a parent. For foreign adoptions, proof may be provided by submitting a copy of the adoption decree and, if applicable, documentation showing the child's change of name. Since rules for foreign adoptions vary by country, alternative and/or additional documentation may be required by the National Settlement Administrator; or
- (iv) for a child that is a stepchild, a certificate of marriage evidencing the marriage of the child's biological parent and the decedent, and a certified birth certificate or documentation evidencing a judicial determination of support and a statement from a person with direct knowledge that verifies that the stepchild (or stepchildren) lived with the decedent in a regular parent-child relationship at the time of the



- decedent's death or describing the reasons why the stepchild did not live with the decedent (such as for medical reasons, to attend school, or for other similar reasons); or
- (v) if dependency is claimed on the basis of the decedent having made regular and substantial contributions to the support of the child, a signed statement from a person with direct knowledge that verifies that the child (or children) lived with the decedent in a regular parent-child relationship at the time of the decedent's death or describing the reason(s) why the child did not live with the decedent (such as for medical reasons, to attend school, or for other similar reason) and one or more of the following proofs:
- evidence of eligibility as a dependent child for benefits under State or Federal programs;
  - cancelled checks, money orders, or receipts for periodic payments received from the decedent for or on behalf of the child;
  - evidence of goods or services that show regular contributions of considerable value by the decedent for or on behalf of the child; or
  - proof of coverage of the child as a family member under the decedent's Federal Employees Health Benefits enrollment or private health insurance.

3. *Spousal Adjustment for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 5 points if the decedent was married on as the date of death as evidenced by the decedent's certified death certificate.

4. *Adult Children Adjustment for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 3 points for each surviving natural or adopted adult child as of the date of death, up to a maximum of 9 points, provided that the Eligible Tort Trust Beneficiary lists the name, date of birth and current address of each surviving natural or adopted adult child on the National Compensation

Claim Form and submits a copy of the decedent's obituary that identifies the surviving natural or adopted adult child(ren) or a signed statement from a person with direct knowledge that the decedent was survived by a natural or adopted adult child(ren) and identifies the surviving child(ren).

5. *Surgical Debridement or Irrigation Surgery, Laminectomy, Discectomy or Hemilaminectomy Adjustment for CATEGORIES I, II and IV*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 2 points for each separate and distinct debridement and/or irrigation surgery without a laminectomy, discectomy or hemilaminectomy, and an additional 4 points for each separate laminectomy, discectomy or hemilaminectomy whether performed contemporaneously with a debridement and/or irrigation surgery or not (if any laminectomy, discectomy or hemilaminectomy involves multiple vertebral levels, the National Settlement Administrator shall also award an additional 2 points for that surgery), after injection from one of the Three Contaminated MPA Lots, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting each of such surgery(ies) and/or procedure(s) after injection. Medical records documenting an incision, drainage or washout shall suffice as proof of a surgical debridement or irrigation surgery. The National Settlement Administrator shall presume that all such surgical debridements and irrigation surgeries after injection from one of the Three Contaminated MPA Lots are the result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each laminectomy, discectomy and hemilaminectomy procedure occurring after injection and before September 30, 2013 is

related to the MPA injection or complication(s) arising therefrom. For laminectomies, discectomies and hemilaminectomies occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that such procedure(s) was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

6. *Anti-Fungal Complication Adjustment for CATEGORIES I, II, III, IV, V and VI*

For Qualified Claims that are awarded 55 base point under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, 10 base points under CATEGORY V, or 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional 3 points if the Tort Trust Beneficiary suffered acute renal insufficiency after treatment with amphotericin B, or 5 points if the Tort Trust Beneficiary suffered acute renal insufficiency requiring temporary dialysis after treatment with amphotericin B, or 10 additional points if the Tort Trust Beneficiary suffered acute renal insufficiency requiring permanent dialysis after treatment with amphotericin B; an additional 5 points if the Tort Trust Beneficiary suffered liver injury/toxicity after treatment with voriconazole,

posaconazole, itraconazole and/or isavuconazole, or 10 points if the Tort Trust Beneficiary suffered liver injury/toxicity requiring liver transplant or placement on the waiting list for a liver transplant after treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole; an additional 5 points if the Tort Trust Beneficiary suffered skin cancer after treatment with voriconazole; and an additional 3 points if the Tort Trust Beneficiary suffered periostitis after treatment with voriconazole provided that the Tort Trust Beneficiary submits medical records documenting (a) acute renal insufficiency within 30 days of the first treatment with amphotericin B, (b) acute renal insufficiency within 30 days of the first treatment with amphotericin B requiring treatment by dialysis (either temporary or permanent) within 180 days of the last treatment with amphotericin B, (c) liver injury/toxicity within 30 days of the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole, (d) liver injury/toxicity within 30 days of the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole requiring liver transplantation or that the Tort Trust Beneficiary was placed on the waiting list for a liver transplant within 180 days of the last treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole, (e) skin cancer within 90 days of the last treatment with voriconazole as evidenced by biopsy, and/or (f) periostitis after treatment with voriconazole. Proof of acute renal insufficiency shall consist of medical records documenting a glomerular filtration rate (“GFR”) of <30 within 30 days following treatment with amphotericin B. The applicable GFR score is the GFR score listed for the patient’s race (non-African American or African American). If GFR scores are not available, medical records documenting a Creatinine Clearance (“CrCl”) level of <30 within 30 days after the first treatment with amphotericin B is

sufficient. Proof of liver injury/toxicity shall consist of medical records documenting a minimum of 5x upper limit of normal (“ULN”) elevation in either the AST or ALT test within 30 days after the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole.

7. *Lengthy Anti-Fungal Treatment Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 2 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 91 -150 days, an additional 3 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 151 -210 days, an additional 4 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 211 -270 days, an additional 5 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 271 -330 days, an additional 6 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 331-390 days, an additional 7 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was

treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 391-450 days, an additional 8 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 451-510 days, an additional 9 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 511-570 days, or an additional 10 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for more than 570 days, provided that the Tort Trust Beneficiary submits medical records documenting the length of treatment with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole after the MPA injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

8. *Lengthy Hospitalization Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points

under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional ½ point, following 5 nights of hospitalization in an acute care hospital after injection from one of the Three Contaminated MPA Lots, for each night of inpatient stay at an acute care hospital, long-term acute care, rehabilitation, hospice or nursing home facility up to 30 nights and 1/3 point for each additional night in excess of 30 nights up to a maximum of 25 points provided that the Eligible Tort Trust Beneficiary submits to the National Settlement Administrator hospital or facility records documenting at least 5 nights of inpatient hospitalization at an acute care hospital and/or records documenting the number of additional nights the decedent stayed in an inpatient acute care hospital, long-term acute care, rehabilitation, hospice or nursing home facility as a result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each such night of hospitalization or facility stay occurring after injection and before September 30, 2013 was the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the hospitalization or facility stay was the result of an unrelated event (*i.e.* auto accident, unrelated illness). For hospitalizations or facility stays for which there is reason to believe are unrelated to the MPA injection or complications arising therefrom and for those occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that the hospitalization or facility stay was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state



only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

9. *Multiple Lumbar Punctures and/or CT Guided Biopsies Adjustment for CATEGORIES I, II, III, IV, V and VI*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, 10 base points under CATEGORY V or 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional  $\frac{1}{2}$  point for each additional lumbar puncture and/or CT guided biopsy more than one after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, up to a maximum of 4 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting two or more lumbar punctures and/or CT guided biopsies after injection and before September 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after

the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

10. *Income Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, or 20 base points under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 1 point if the Tort Trust Beneficiary's 2012 or 2013 earned income was 10% to 19% less than their 2011 earned income, an additional 2 points if the Tort Trust Beneficiary's earned income was 20% to 29% less than their 2011 earned income, an additional 3 points if the Tort Trust Beneficiary's earned income was 30% to 39% less than their 2011 earned income, an additional 4 points if the Tort Trust Beneficiary's earned income was 40% to 49% less than their 2011 earned income, an additional 5 points if the Tort Trust Beneficiary's earned income was 50% to 59% less than their 2011 earned income, an additional 6 points if the Tort Trust Beneficiary's earned income was 60% to 69% less than their 2011 earned income, an additional 7 points if the Tort Trust Beneficiary's earned income was 70% to 79% less than their 2011 earned income, an additional 8 points if the Tort Trust Beneficiary's earned income was 80% to 89% less than their 2011 earned income, or an additional 9 points if the Tort Trust Beneficiary's earned income was 90% or more less than their 2011 earned income, provided that the Eligible Tort Trust Beneficiary submits to the National Settlement Administrator, the Tort Trust Beneficiary's income tax return for 2011(whether filed jointly or single) or the Tort Trust Beneficiary's 2011 W-2(s), 1099(s) and/or 10-K(s), and the same documentation for either of the years 2012 or 2013. Earned

income shall include wages, salaries, tips, and other taxable employee pay (Form 1040, line 7), business income or loss (Form 1040, line 12), partnership or S corporation income (Form 1040, line 17), and other income (Form 1040, line 21). For CATEGORY I Qualified Claims, if the death occurred during 2012, earned income for 2013 will be deemed to be zero and no documentation of decedent's 2013 income will be required. The National Settlement Administrator shall presume that the decrease in earned income is the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the decrease in earned income was the result of an unrelated event (*i.e.* layoff, forced work reduction, planned retirement).

11. *Stroke Adjustment for CATEGORIES II and III*

For Qualified Claims awarded 40 base points under CATEGORY II or 30 base points under CATEGORY III, the National Settlement Administrator shall also award an additional 12 points to any Tort Trust Beneficiary who suffered a cerebrovascular accident/stroke (but not a transient ischemic attack only) after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of cerebrovascular accident/stroke (but not a transient ischemic attack only). If the cerebrovascular accident/stroke occurred on or before December 31, 2012, the National Settlement Administrator shall presume that the cerebrovascular accident/stroke was the result of the MPA injection or complication(s) arising therefrom unless there is a reason to believe that the cerebrovascular accident/stroke was the result of an unrelated event (*i.e.* the Tort Trust Beneficiary has a past history of cerebrovascular/accident/stroke). For cerebrovascular accidents/strokes for which there is reason to believe are unrelated to the

MPA injection or complications arising therefrom and for those occurring after December 31, 2012, proof deemed sufficient by the National Settlement Administrator that the cerebrovascular accident/stroke was the result of the MPA injection or complication(s) therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

12. *Sacroiliac Joint Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 4 points if the Tort Trust Beneficiary suffered a fungal infection of a sacroiliac joint or surrounding ligaments/bones after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting the MPA injection into a sacroiliac joint or surrounding ligaments/bones and that the fungal infection occurred in a sacroiliac joint or surrounding ligaments/bones after the MPA injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort

Trust Beneficiary's medical records state only that a steroid was administered on specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

13. *Arachnoiditis Adjustment and Neurogenic Bowel and/or Bladder Sub-Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 10 points if the Tort Trust Beneficiary suffered from arachnoiditis after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a) a diagnosis of arachnoiditis or documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI after injection from one of the Three Contaminated MPA Lots, and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment. In addition, for Qualified Claims that are awarded 10 points for arachnoiditis, the National Settlement Administrator shall also award an additional 2 points if the Tort Trust Beneficiary suffered from neurogenic bowel and/or neurogenic bladder dysfunction after injection from one of the Three Contaminated MPA Lots, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of neurogenic bowel and/or neurogenic bladder after September 1, 2012 and before December 31, 2013 and (a) in the case of neurogenic bowel, manifestation of symptoms

including significant constipation, fecal incontinence, fecal impaction, and/or alternating diarrhea lasting for more than 6 months, or (b) in the case of neurogenic bladder, manifestation of symptoms of urinary retention and/or urinary incontinence lasting more than 6 months and which required intermittent or regular urinary catheterization. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

14. *Vertebral Osteomyelitis Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 5 points if the Tort Trust Beneficiary suffered from vertebral osteomyelitis after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a) a diagnosis of vertebral osteomyelitis after injection from one of the Three Contaminated MPA Lots and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical

records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

*15. Peripheral Joint Infection Adjustment for CATEGORIES II, III and IV*

For Qualified Claims awarded 40 base points under CATEGORY II, 30 base points under CATEGORY III, or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 3 points if the Tort Trust Beneficiary also suffered from a peripheral joint fungal infection after injection from one of the Three Contaminated MPA Lots provided the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a)(i) a diagnosis of peripheral joint fungal infection (including, but not limited to, osteomyelitis and septic arthritis) after injection from one of the Three Contaminated MPA Lots into the osteoarticular structure of a peripheral joint (including the bursa and peripheral nerves) and (ii) that the Tort Trust Beneficiary received anti-fungal treatment, or (b) proof that the Tort Trust Beneficiary was listed on the a state list of NECC's peripheral joint infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall

presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

16. *Hip Infection Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 8 points if the Tort Trust Beneficiary's fungal infection occurred in the hip/bursa after injection from one of the Three Contaminated MPA Lots into the hip/bursa provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting that the Tort Trust Beneficiary received a MPA injection in the hip/bursa and that the fungal infection occurred in the hip/bursa after the injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

17. *Multiple Joint Fungal Infections Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 4 points for each additional



peripheral joint fungal infection after injection from one of the Three Contaminated MPA Lots into an additional peripheral joint, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of a fungal infection of an additional peripheral joint (including, but not limited to, osteomyelitis and septic arthritis) after injection into the osteoarticular structure of the additional peripheral joint (including the bursa and the peripheral nerves). If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists ), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

18. *Debridement/Incision Surgery Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 2 points for each separate and distinct (1) debridement/incision of a joint and/or associated bursa, with or without prosthesis placement; (2) an additional 3 points for each distinct synovectomy, whether or not performed contemporaneously with a debridement and/or irrigation surgery; and /or (3) an additional 4 points for each partial or full arthroplasty with or without prosthesis placement, whether or not performed contemporaneously with a debridement

and/or irrigation surgery or a synovectomy, after injection of one or more of the Three Contaminated MPA Lots into a peripheral joint, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting such surgery(ies) and/or procedure(s) after injection from one of the Three Contaminated MPA Lots. Medical records documenting an irrigation, drainage or washout shall suffice for a debridement/incision surgery. The National Settlement Administrator shall presume that all debridement/incision surgeries after injection from one of the Three Contaminated MPA Lots are the result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each such synovectomy or arthroplasty procedure occurring after injection and before September 30, 2013 is related to the MPA injection or complication(s) arising therefrom. For synovectomies and arthroplasties occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that such procedure(s) was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

19. *Hospitalization Adjustment for CATEGORY VI*

For Qualified Claims awarded 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional ½ point for each night the Tort Trust Beneficiary was hospitalized at an acute care hospital after injection of one of the Three Contaminated MPA Lots and before April 30, 2013, up to a maximum of 3 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator hospital records documenting the number of nights hospitalized at an acute care hospital after injection and before April 30, 2013. The National Settlement Administrator shall presume that each such hospitalization was the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the hospitalization was the result of an unrelated event (*i.e.*, auto accident, unrelated illness). For those hospitalizations for which there is reason to believe were the result of an unrelated event, proof deemed sufficient by the National Settlement Administrator that the hospitalization was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

20. *Anti-Fungal Treatment Adjustment for CATEGORY VI*

For Qualified Claims awarded 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional 1 point if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 1 - 90 days, an additional 2 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 91 - 180 days, an additional 3 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 181 - 270 days, or an additional 4 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for more than 270 days, provided that the Tort Trust Beneficiary submits medical records documenting the length of treatment with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole after the MPA injection and before September 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots

occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

**V. Eligible Claims Involving Other Contaminated NECC Products Apart From One of the Three Contaminated MPA Lots**

**A. Proof of Exposure to a Contaminated Product Compounded by NECC After January 1, 2006 Apart From One of the Three Contaminated MPA Lots**

In order for an Eligible Claim that does not involve an injection or injections from one of the Three Contaminated MPA Lots to be deemed a Qualified Claim, the Eligible Tort Trust Beneficiary must submit to the National Settlement Administrator medical records or other records documenting that the Tort Trust Beneficiary was administered a specified lot of NECC product that was compounded by NECC after January 1, 2006 (*i.e.*, a letter from a clinic, hospital or doctor's office informing the Tort Trust Beneficiary that he/she was administered a specified lot of NECC product). The Tort Trust Beneficiary must also submit proof deemed sufficient by the National Settlement Administrator that the administered lot of NECC product was contaminated. Examples of such satisfactory proof are the nine lots of non-MPA NECC products which have been determined by the CDC to have been contaminated (see attached Addendum A), and NECC's outside testing laboratory's determination that some lots of NECC's products were contaminated during the summer and fall of 2012 (see attached Addendum B). If the requirements listed above are satisfied, the Tort Trust Beneficiary shall be entitled to make a claim for one of the seven Base Point Categories designed for the Three Contaminated MPA Lots described in Section IV.B herein. The Tort Trust Beneficiary must satisfy the proof requirements for one of the seven Base Point Categories and adjustments applied for, except the Tort Trust Beneficiary need not provide proof of an injection from one of the Three

Contaminated MPA Lots and references to an “injection from one of the Three Contaminated MPA Lots” in the seven Base Categories proof requirements will be read as “administration from a contaminated lot of NECC product.”

B. Claims Involving an Injection or Injections of One or More of the Three Contaminated MPA Lots and Administration of a Contaminated Lot of NECC Product Apart from One of the Three Contaminated MPA Lots

In the event that a Tort Trust Beneficiary has received both an injection or injections from one or more of the Three Contaminated MPA Lots and also has been administered another contaminated NECC product, the Tort Trust Beneficiary may apply for one of the seven Base Point Categories only for either the MPA injection(s) or for the other contaminated NECC product.

**VI. Eligible Claims Involving Bacterial Infection and Bacterial Meningitis**

An Eligible Tort Trust Beneficiary who claims that he/she suffered from a bacterial infection or bacterial meningitis after being administered a contaminated lot of NECC product must submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary was administered a specified lot of NECC product that was compounded after January 1, 2006 (*i.e.*, a letter from a clinic, hospital, or doctor’s office informing the Tort Trust Beneficiary that he/she had received a specified lot of NECC product). The Tort Trust Beneficiary must also submit to the National Settlement Administrator proof deemed sufficient by the National Settlement Administrator that the lot of NECC product administered to the Tort Trust Beneficiary was contaminated with a specific type of bacteria. Examples of such contaminated lots of NECC products are the six lots of non-MPA NECC products that have been determined by the CDC and FDA to have been contaminated with various specific types of bacteria (see Addendum A), Lot 09252012@50 of Bacitracin (stock) 50ku/20 MI solution that ARL found to be contaminated with *Paenibacillus borealis*, and Lot

08102012@51 of MPA that was found to be contaminated with *Bacillus subtilis* and *Bacillus pumilus*. The Tort Trust Beneficiary must also submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary was infected with the same specific type of bacteria that was found to be in the contaminated lot of NECC product administered to the Tort Trust Beneficiary (*i.e.*, *Bacillus subtilis* or *Bacillus pumilus* for MPA Lot 08102012@51). If the requirements listed above are satisfied, the Tort Trust Beneficiary shall be entitled to make a claim for one of the seven Base Point Categories designed for the Three Contaminated MPA Lots. The Tort Trust Beneficiary must satisfy the proof requirements for the one of the seven Base Point Categories and adjustments applied for subject to the following:

1. *For CATEGORY I Claims:*

- (i) the death certificate must document the immediate or underlying cause of death as “bacterial infection,” “bacterial meningoenzephalitis,” “bacterial enzephalitis,” or “bacterial meningitis,” or the medical records must document a diagnosis of bacterial infection or bacterial meningitis, bacterial meningoenzephalitis or bacterial enzephalitis after administration from a contaminated lot of NECC product. No medical documentation of fungal meningitis, fungal meningoenzephalitis, fungal enzephalitis, or spinal or paraspinal fungal infection is required. No documentation of anti-fungal treatment is required;
- (ii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available.

2. *For CATEGORY II, III AND IV Claims:*

- (i) the medical records must document a diagnosis of bacterial meningitis, bacterial meningoencephalitis, bacterial encephalitis, or spinal or paraspinal bacterial infection after administration from a contaminated lot of NECC product. No medical documentation of fungal meningitis, fungal meningoencephalitis, fungal encephalitis, or spinal or paraspinal fungal infection is required. No documentation of anti-fungal treatment is required;
- (ii) for the Sacroiliac Joint Infection Adjustment, the medical records must document injection from a contaminated lot of NECC product into the sacroiliac joint or surrounding ligaments/bones and that the bacterial infection occurred in the sacroiliac joint or surrounding ligaments/bones after injection. No documentation of fungal infection in the sacroiliac joint is required;
- (iii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available;
- (iv) for the Peripheral Joint Infection Adjustment, the medical records must document a peripheral joint bacterial infection after injection from a contaminated lot of NECC product into the peripheral joint. No documentation of a peripheral joint fungal infection is required.

3. *For CATEGORY V Claims:*



- (i) the medical records must document a diagnosis of a peripheral joint (*e.g.*, hip, knee, shoulder, or ankle) bacterial infection after injection from a contaminated lot of NECC product into the osteoarticular structure of a peripheral joint (including the bursa and peripheral nerves). No documentation of a peripheral joint fungal infection or of anti-fungal treatment is required;
- (ii) for the Hip Infection Adjustment, the medical records must document a bacterial infection in the hip/bursa after injection from a contaminated lot of NECC product into the hip/bursa. No documentation that a fungal injection occurred in the hip/bursa is required;
- (iii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available;
- (iv) for the Multiple Joint Fungal Infections Adjustment, the medical records must document a bacterial infection in the additional peripheral joint after injection from a contaminated lot of NECC product into the osteoarticular structure of an additional peripheral joint (including the bursa and the peripheral nerves). No documentation of a fungal infection of an additional peripheral joint is required.

4. *For CATEGORY VI Claims:*

There will be no Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available.

**VII. Claims Assistance Program**

The National Settlement Administrator shall develop, staff and maintain a program for providing claims assistance to Tort Trust Beneficiaries (“Claims Assistance Program”). This program shall be a part of the Claims Resolution Facility, staffed by employees of the Claims Resolution Facility, and is intended to provide assistance to all Tort Trust Beneficiaries regarding the Claims Resolution Facility procedures, eligibility requirements, submission requirements (including the documentation required), denials, deficiencies, the process for curing deficiencies, obtaining re-reviews, requesting reconsideration under a different Base Point Category and appeal procedures in the event of a final denial of a claim, and the status of a Tort Trust Beneficiary’s claim. The Claims Assistance Program staff shall not provide legal advice or tax advice to Tort Trust Beneficiaries.

### **VIII. Initial Payments On Qualified Claims**

A. As soon as practicable after the Claims Deadline and after completing his/her initial review of claims, the National Settlement Administrator shall compute a tentative dollar value of each Claimed Point (“Tentative Point Value”) according to the following formula: (i) calculate the sum of all Claimed Points in all of the Eligible Claims (“Summed Points”), (ii) multiply the Summed Points by a factor of 1.5 (“Enhanced Points”), and (iii) divide the National Fund Net Trust Proceeds (*i.e.*, the amount available for distribution to Tort Trust Beneficiaries at the time the computation is made) by the number of Enhanced Points:

$$[\text{Tentative Point Value} = [\text{National Fund Net Trust Proceeds} \div \text{Enhanced Points}]]$$

B. The National Settlement Administrator shall then evaluate Tort Claims in the order that they were received.

C. If an Eligible Claim is allowed in full, the Tort Trust Beneficiary’s Claimed Points shall be deemed to be Approved Points, and the National Settlement Administrator shall multiply the Approved Points by the Tentative Point Value to determine the amount of the Initial

Payment to the Claimant. The National Settlement Administrator shall notify said Tort Trust Beneficiary of the allowance of the claim in full, the amount of Approved Points, the amount of the Initial Payment, and the amount of the Initial Payment constitutes interim compensation and that the Tort Trust Beneficiary may receive additional compensation after the Claims Process is completed and all appeals from the National Settlement Administrator's final determinations have been resolved.

D. Notwithstanding anything herein to the contrary, no distribution shall be made to a Tort Trust Beneficiary if such Tort Trust Beneficiary has not returned a signed form W-9 to the National Settlement Administrator.

E. If a completed W-9 form has been received by the National Settlement Administrator, the National Settlement Administrator shall notify the Tort Trustee of the Allowed Claim and that a check should be sent to the Tort Trust Beneficiary (or, if represented by an attorney, made payable jointly to the Tort Trust Beneficiary and the attorney or law firm and sent to the attorney) in the amount of the Initial Claim Value, subject to the provisions of the Plan and the Tort Trust Agreement.

#### **IX. Provisional Denials**

A. Eligible Claims not approved in full by the National Settlement Administrator shall be deemed to be provisionally denied ("Provisional Denials"). Provisional Denials shall consist of Eligible Claims denied in whole (*e.g.*, claim did not meet the proof requirements for a Base Point Category) or denied in part (*e.g.*, an applied-for adjustment was not awarded).

B. For each Eligible Claim denied in part, the National Settlement Administrator shall sum the Points that have been approved ("Approved Points") and determine the Initial

Claim Value of the claim as approved by multiplying the Approved Points by the Tentative Point Value.

C. A “Notice of Provisional Denial” identifying the specific reason(s) for the provisional denial and, for claims denied in part, stating the number of Approved Points and the Initial Claim Value as determined in accordance with Section IX.B herein, shall be sent to the Tort Trust Beneficiary. Such notice shall also inform the Tort Trust Beneficiary of (a) the procedures and deadlines established pursuant to Section X herein for correcting deficiencies, obtaining a re-review for error, and obtaining reconsideration under a different Base Point Category, and (b) the availability of assistance through the Claims Assistance Program. Such Notices of Provisional Denial shall inform the Tort Trust Beneficiary that if the Tort Trust Beneficiary fails to follow the procedures established pursuant to Section X below within 90 days of the Notice of Provisional Denial then the Provisional Denial will be deemed to be a final determination and the Tort Trust Beneficiary will have waived any right to appeal to the Appeals Administrator and, for claims denied in part, that the Initial Claim Value will be paid after 90 days from the date of the Notice of Provisional Denial.

D. The Notice of Provisional Denial shall also inform Tort Trust Beneficiaries that the compensation payable on any Eligible Claim that is approved, in whole or in part, after being re-submitted for reconsideration under a different Base Point Category may be reduced by the National Settlement Administrator pursuant to Section XII.B herein.

**X. Attempts to Cure Deficiencies, Requesting Re-review For Error or Requesting Reconsideration Under a Different Base Point Category.**

A. In the event of a Provisional Denial, a Tort Trust Beneficiary shall have ninety (90) days from the date of the Notice of Provisional Denial to submit to the National Settlement Administrator (a) documentation that purports to cure some or all of the noticed deficiencies

(“attempt to cure deficiency”), (b) a request for re-review for error, which request states fully the grounds for such request (“request for re-review for error”), or (c) a request for reconsideration under a different Base Point Category, which shall be accompanied by a new National Compensation Claim Form and all required documentation in support of the new claim (“Resubmitted Claim”). A Tort Trust Beneficiary requesting reconsideration under a different Base Category shall also write or type the following at the top of the new National Compensation Claim Form: “RE-SUBMITTED CLAIM – NEW BASE POINT CATEGORY.” All such documentation, requests and Resubmitted Claims must be received by the National Settlement Administrator by the Deadline imposed by this subsection.

B. The National Settlement Administrator shall evaluate and make a final determination on attempts to cure deficiencies and requests for re-reviews for error in the order in which they are received. A Notice of Final Determination shall then be sent to such Tort Trust Beneficiary, which Notice shall contain the following information (as applicable): (a) the National Settlement Administrator’s final determination on the Tort Trust Beneficiary’s Tort Claim, which may constitute approval in whole, approval in part, or denial in whole, and the reason(s) therefor, (b) the number of Approved Points (if any), (c) that payment of the claim (if any) will be made, subject to the provisions of the Plan and the Tort Trust Agreement, after 90 days if no appeal is sought by the Tort Trust Beneficiary pursuant to Section XI herein, (d) in the event of a denial in whole or in part, notice of the appeals procedure available pursuant to Section XI herein; and (e) the availability of assistance through the Claims Assistance Program.

C. In order to encourage the accuracy of originally-filed Tort Claims, to reduce the administrative costs to the Tort Trust of re-considering claims under different Base Point Categories, and to be able to make Initial Payments to Tort Trust Beneficiaries, the National

Settlement Administrator shall hold for review all requests for reconsideration under a different Base Point Category until all other claims (including those involving attempts to cure deficiencies and requests for re-review for error pursuant to Section X.B herein, but not claims that are appealed to the Appeals Administrator) have been finally determined. The National Settlement Administrator shall thereafter review and make a final determination on all requests for reconsideration under a different Base Point Category in the order that they were received. A Notice of Final Determination shall then be sent to such Tort Trust Beneficiaries, which notice shall contain the following information: (a) the National Settlement Administrator's final determination on the Tort Trust Beneficiary's claim, which may constitute approval in whole, approval in part, or denial in whole, and the reason(s) therefore; (b) the number of Approved Points (if any); (c) in the event of a denial in whole or in part, notice of the appeals procedure available pursuant to Section XI herein; (d) notice that any awards on requests for reconsideration under a different base point category, whether allowed in whole or in part, may be reduced pursuant to Section XII.B herein and will not be paid until the Final Payments to Tort Trust Beneficiaries have been calculated; and (e) the availability of the Claims Assistance Program.

D. In the event that a Tort Trust Beneficiary does not submit to the National Settlement Administrator, pursuant to Section X.A., herein, within ninety (90) days from the date of the Notice of Provisional Denial, an attempt to cure a deficiency, a request for re-review for error or a request for reconsideration under a different Base Point Category, the National Settlement Administrator's Provisional Denial shall automatically become a final determination and the Tort Trust Beneficiary shall have waived any right to exercise the appeal procedures set out in Section XI herein. If any such provisional denial that automatically becomes a final

determination included an award of Approved Points and an Initial Claim Value, the National Settlement Administrator shall notify the Tort Trustee of the Approved Claim and that a check should be sent to the Tort Trust Beneficiary (or, if represented by an attorney, a check made payable jointly to the Tort Trust Beneficiary and the attorney or law firm and sent to the attorney) in the amount of the Initial Claim Value for said claim subject to the provisions of the Plan and the Tort Trust Agreement.

## **XI. Appeals From Final Determinations**

A. Any Tort Trust Beneficiary aggrieved by a final determination made by the National Settlement Administrator who has not waived the right of appeal pursuant to the provisions of Section X.D herein shall have the right to appeal such final determination to the Appeals Administrator. To be eligible for consideration by the Appeals Administrator, any such appeal must be in the form of a written statement explaining the Tort Trust Beneficiary's contentions and must be received by the Appeals Administrator on or before thirty (30) days after the date of the National Settlement Administrator's final determination. The Appeals Administrator shall notify the National Settlement Administrator of any such appeal and the National Settlement Administrator shall promptly forward to the Appeals Administrator a copy of the Tort Trust Beneficiary's claim file for each appeal.

B. For claims denied in full, the Appeals Administrator shall (1) perform a *de novo* evaluation of the denial in full in accordance with the applicable provisions of Sections III-VI herein, (2) if no upward adjustments to a Base Point Category were claimed, make a final determination as to whether the claim should be allowed and the number of Approved Points allowed for each such claim, which may be reduced by the National Settlement Administrator in accordance with Section XII.B herein for any claim that was approved after reconsideration

under a different Base Point Category, (3) if upward adjustments to a Base Point Category were claimed, make a final determination as to whether the claim should be allowed under the Base Point Category claimed, and, if such claim is so allowed, remand the matter to the Settlement Administrator to allow him or her to issue a provisional determination on the upward adjustments claimed, and (4) inform the respective Tort Trust Beneficiary and the National Settlement Administrator in writing of the action taken by the Appeals Administrator and the number of Approved Points, if any.

C. For claims denied in part, the Appeals Administrator shall (1) perform a *de novo* evaluation of the partial denial in accordance with the applicable provisions of Sections III-VI herein, (2) make a final determination of the number of Approved Points allowed for each such claim, which may be reduced by the National Settlement Administrator in accordance with Section XII.B herein for any claim that was approved after reconsideration under a Different Base Category, and (3) inform the respective Tort Trust Beneficiaries and the National Settlement Administrator in writing of such final determination and the number of Approved Points. The Appeals Administrator's final determination shall be final and binding.

## **XII. Final Payments to Tort Trust Beneficiaries**

A. Within 120 days after all claims are finally determined, all appeals are resolved by the Appeals Administrator, and the final resolution of any appeals of the Bankruptcy Court's Confirmation Order, the National Settlement Administrator shall compute the final dollar value of each Approved Point ("Final Point Value") by dividing the Net Distribution Amount (*i.e.*, the total amount previously paid to Tort Trust Beneficiaries and the amount available to be paid in compensation to Tort Trust Beneficiaries) by the sum of (i) all Approved Points for claims approved in full pursuant to Section VIII.C herein, (ii) all Approved Points for claims finally



determined by the National Settlement Administrator pursuant to Section X.A-D herein, including those claims that were re-submitted for review under a different Base Point Category and (iii) all Approved Points for claims finally determined by the Appeals Administrator pursuant to Section XI herein.

B. In the event that the computation in Section XII.A herein yields a final dollar value of each Approved Point that is less than the Tentative Point Value, then the National Settlement Administrator shall reduce, on a *pro rata* basis, the Approved Points awarded on claims that were re-submitted for review under a different Base Point Category in such amount as is required for the computation in Section XII.A herein to yield a final dollar value of each Approved Point that is equal to the Tentative Point Value. Such final dollar shall be considered the Final Point Value.

C. In the event that the computation in Section XII.A herein yields a final dollar value of each Approved Point that is greater than the Tentative Point Value, then such final dollar value of each Approved Point shall be considered the Final Point Value.

D. The National Settlement Administrator shall then determine the final compensation amount for each Qualified Claim ("Final Compensation Amount") by multiplying the Approved Points times the Final Point Value on each Qualified Claim.

E. Promptly thereafter, the National Settlement Administrator shall notify the Tort Trustee to make the following disbursements:

1. If the Final Point Value exceeds the Tentative Point Value, then each Tort Trust Beneficiary who received an Initial Payment pursuant to Section VIII.C or X.D above shall be paid (or, if represented by an attorney, paid jointly with the attorney or law firm) an additional amount equivalent to the difference between the Tort Trust

Beneficiary's Final Compensation Amount and the Initial Payment, subject to the provisions of the Plan and the Tort Trust Agreement.

2. All other Tort Trust Beneficiaries whose Tort Claim has been approved in whole or in part shall be paid (or if represented by an attorney, paid jointly with the attorney or law firm) an amount equivalent to the Tort Trust Beneficiary's Final Compensation Amount subject to the provisions of the Plan and the Tort Trust Agreement.

F. Additional Assets Received by the Tort Trust after the Final Payments have been made to the Tort Trust Beneficiaries may be disbursed on a pro rata basis to Tort Trust Beneficiaries or otherwise, pursuant to the provisions of the Plan and the Tort Trust Agreement.

### **XIII. Prevention and Detection of Fraud**

A. The National Settlement Administrator may institute claim auditing procedures and other procedures to detect and prevent the allowance of fraudulent claims. All claims must be signed under the pains and penalties of perjury. The submission of a fraudulent claim will violate the criminal laws of the United States, including the criminal provisions applicable to Bankruptcy Crimes, 18 U.S.C. § 152, and subject those responsible to criminal prosecution in the federal courts. If the National Settlement Administrator determines that a claim is fraudulent, the National Settlement Administrator shall deny the claim and so inform the Tort Trust Beneficiary and the Tort Trustee.

B. The National Settlement Administrator shall have the authority to request the Tort Trust Beneficiary to submit additional medical, hospital, facility or other records in order to make a determination of allowance or denial of any claim. If the Tort Trust Beneficiary refuses to or fails to respond to such a request within ninety (90) days or if the National Settlement

Administrator determines that a Tort Trust Beneficiary's response is inadequate, the National Settlement Administrator shall take such actions as he or she deems appropriate on the claim and notify the Tort Trust Beneficiary of the action and basis therefore.

C. The National Settlement Administrator may conduct random audits to verify supporting documentation submitted (including death certificates, medical and other records) by randomly selecting claims and may audit individual claims or groups of claims.

D. All Tort Trust Beneficiaries must certify to the National Settlement Administrator on the National Compensation Claim Form that the Tort Trust Beneficiary has not transferred his or her right to recover from the Released Parties with respect to his or her Claim such that the Claim can be asserted by another person or entity. The fact that a Tort Trust Beneficiary has executed a "subrogation" agreement with a health insurer or that a statutory provision grants to any governmental entity rights of subrogation shall not of itself be construed as a transfer of the Tort Trust Beneficiary's right to recover.

#### **XIV. Closure of the Claims Resolution Facility**

Within ninety (90) days after all Qualified Claims have been paid by the Tort Trust, the National Settlement Administrator shall wind up the affairs of the Claims Resolution Facility and the National Settlement Administrator and the Tort Trustee shall file a joint final report with the Bankruptcy Court and the District Court. The final report shall specify the total number of Claims filed in each of the seven Base Point Categories, the Tentative Point Value of each point, the Final Point Value of each point, the total number of Qualified Claims in each Base Point Category, the total number of points awarded in each Base Point Category, and the total amounts paid to each Tort Trust Beneficiary in each Base Point Category.

**XV. Notices to the National Settlement Administrator**

To be effective, all requests, notices, Claims, and Resubmitted Claims to or upon the National Settlement Administrator and/or the Claims Resolution Facility shall be in writing, and unless otherwise expressly provided herein, shall be deemed to have been duly given or made when actually delivered to the National Settlement Administrator at the address set forth below:

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**XVI. Notices to the Appeals Administrator**

To be effective, an appeal made to the Appeals Administrator shall be in writing and, unless otherwise expressly provided herein, shall be deemed to have been duly given or made when actually delivered to the Appeals Administrator at the address set forth below:

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Home Drugs Drug Safety and Availability Multistate outbreak of fungal meningitis and other infections

## Drugs

### Multistate outbreak of fungal meningitis and other infections



#### Laboratory Testing and Results

[12-12-2012] FDA and CDC have identified bacterial and/or fungal contamination in unopened vials of betamethasone, triamcinolone solutions distributed and recalled from NECC. These include bacteria known as *Bacillus*, and fungal species including *Aspergillus tubingensis*, *Aspergillus fumigatus*, *Cladosporium* species, and *Penicillium* species. Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *Aspergillus fumigatus*, are known to cause disease in humans. It is not known how product contamination with these organisms could affect patients clinically. See CDC's Advice for Clinicians<sup>1</sup>.

CDC and FDA Laboratory-Confirmed Organisms from Product Samples		
Laboratory-Confirmed Organisms from Product Samples Associated with NECC Recalled Lots of Betamethasone, Triamcinolone, and Triamcinolone Solutions		
Medication	Lot Number	Bacterial and Fungal Contamination
Betamethasone 6 mg/mL injectable -5 mL per vial	08202012@141	<i>Paenibacillus pabuli/amolyticus</i> , <i>Bacillus idriensis</i> , <i>Bacillus flexus</i> , <i>Bacillus simplex</i> , <i>Lysinibacillus</i> sp., <i>Bacillus niacini</i> , <i>Kocuria rosea</i> , <i>Bacillus lentus</i>
Betamethasone 6 mg/mL injectable -5 mL per vial	07032012@22	<i>Bacillus niabensis</i> , <i>Bacillus circulans</i>
Betamethasone 12 mg/mL injectable - 5 mL per vial	07302012@52	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Paenibacillus barengoltzii/timonensis</i>
Betamethasone 6mg/mL injectable - 5 mL per vial	08202012@44	<i>Bacillus lentus</i> , <i>Bacillus firmus</i> , <i>Bacillus pumilus</i>
Betamethasone 6 mg/mL injectable - 5 mL per vial	08152012@84	<i>Penicillium</i> sp., <i>Cladosporium</i> sp.
Triamcinolone 40mg/mL injectable - 1 mL per vial	06062012@6	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Bacillus nealsonii</i> , <i>Bacillus subtilis</i> group, <i>Bacillus firmus</i>
Triamcinolone 40 mg/mL injectable - 2 mL per vial	08172012@60	<i>Aspergillus tubingensis</i> , <i>Penicillium</i> sp.
Triamcinolone 40mg/mL injectable - 10 mL per vial	08242012@2	<i>Aspergillus fumigatus</i>
Cardioplegia solution 265.5 mL per bag	09242012@55	<i>Bacillus halmopalus/horikoshii</i> , <i>Brevibacillus choshinensis</i>

#### Related Information

- FDA Form 483 for New England Compounding Center (PDF - 1.7MB)<sup>2</sup>
- Archive of Updates on Fungal Meningitis Outbreak<sup>3</sup>
- List of Recalled Products Related to Fungal Meningitis Outbreak<sup>4</sup>
- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information<sup>5</sup>

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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U.S. Food and Drug Administration  
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 Silver Spring, MD 20993  
 Ph. 1-888-INFO-FDA (1-888-463-6332)  
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U.S. Department of Health & Human Services

#### Links on this page:

1. <http://www.cdc.gov/medicationsafety/recalls/necc/#advice>
2. [/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM325980.pdf](#)
3. [/Drugs/DrugSafety/FungalMeningitis/ucm325037.htm](#)
4. [/Drugs/DrugSafety/ucm322752.htm](#)
5. [/Drugs/DrugSafety/DrugShortages/ucm323947.htm](#)

## Addendum B

**ARL LABORATORY**  
**CONFIRMED CONTAMINATION FROM NECC NON-MPA PRODUCT SAMPLES**

<b>Medication</b>	<b>Lot Number</b>
Bacitracin 50,000 units in 20ml 0.9% Sodium Chloride	07232012@125
Polym-Bari (STOCK) 3L *Glen Falls* 1.5mu-30KU/30mL solution	08062012@115
Polymyxin/Bacitracin *Winchester* 1mu-50KU/20mL solution	08272012@87
Sodium Bicarbonate 150mEq/1000ml in Sterile Water for injection	08282012@110
Bacitracin (STOCK) 50KU/20mL solution	09252012@90
Potassium Chloride Sterile Solution Concentrate, USP 2mEq/ml (500mEq)	09252012@94